

We Claim:

1. A method of detecting the presence of a target PS116 polynucleotide in a test sample, comprising:
  - 5 (a) contacting said test sample with at least one PS116-specific polynucleotide or complement thereof; and
  - (b) detecting the presence of said target PS116 polynucleotide in the test sample, wherein said PS116-specific polynucleotide has at least 50% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NOS 10 1-12, and fragments or complements thereof.
2. The method of claim 1, wherein said target PS116 polynucleotide is attached to a solid phase prior to performing step (a).
- 15 3. A method for detecting mRNA of PS116 in a test sample, comprising:
  - (a) performing reverse transcription with at least one primer in order to produce cDNA;
  - (b) amplifying the cDNA obtained from step (a) using PS116 20 oligonucleotides as sense and antisense primers to obtain PS116 amplicon; and
  - (c) detecting the presence of said PS116 amplicon, wherein the PS116 oligonucleotides utilized in steps (a) and (b) have at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NOS 1-12, and fragments or complements thereof.
- 25 4. The method of claim 3, wherein said test sample is reacted with a solid phase prior to performing one of steps (a), (b), or (c).
- 30 5. The method of claim 3, wherein said detection step comprises utilizing a detectable label capable of generating a measurable signal.
6. A method of detecting a target PS116 polynucleotide in a test sample suspected of containing said target, comprising:
  - (a) contacting said test sample with at least one PS116 oligonucleotide 35 as a sense primer and with at least one PS116 oligonucleotide as an anti-sense primer and amplifying to obtain a first stage reaction product;

- (b) contacting said first stage reaction product with at least one other PS116 oligonucleotide to obtain a second stage reaction product, with the proviso that the other PS116 oligonucleotide is located 3' to the PS116 oligonucleotides utilized in step (a) and is complementary to said first stage reaction product; and
- 5 (c) detecting said second stage reaction product as an indication of the presence of the target PS116 polynucleotide, wherein the PS116 oligonucleotides utilized in steps (a) and (b) have at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NOS 1-12, and fragments or complements thereof.
- 10 7. The method of claim 6, wherein said test sample is reacted with a solid phase prior to performing one of steps (a), (b), or (c).
- 15 8. The method of claim 6, wherein said detection step comprises utilizing a detectable label capable of generating a measurable signal.
9. The method of claim 8, wherein said detectable label is reacted to a solid phase.
- 20 10. A test kit useful for detecting PS116 polynucleotide in a test sample, comprising a container containing at least one PS116 polynucleotide having at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NOS 1-12, and fragments or complements thereof.
- 25 11. A purified polynucleotide or fragment thereof derived from a PS116 gene, wherein said polynucleotide is capable of selectively hybridizing to the nucleic acid of said PS116 gene and has at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NOS 1-12, and fragments or complements thereof.
- 30 12. The purified polynucleotide of claim 11, wherein said polynucleotide is produced by recombinant techniques.
- 35 13. The purified polynucleotide of claim 11, wherein said polynucleotide is produced by synthetic techniques.

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14. The purified polynucleotide of claim 11, wherein said polynucleotide comprises a sequence encoding at least one PS116 epitope.

5 15. A recombinant expression system comprising a nucleic acid sequence that includes an open reading frame derived from PS116 operably linked to a control sequence compatible with a desired host, wherein said nucleic acid sequence has at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NOS 1-12, and fragments or complements thereof.

10 16. A cell transfected with the recombinant expression system of claim 15.

15 17. A PS116 polypeptide having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, SEQUENCE ID NO 29, and fragments thereof.

20 18. The polypeptide of claim 17, wherein said polypeptide is produced by recombinant techniques.

19. The polypeptide of claim 17, wherein said polypeptide is produced by synthetic techniques.

25 20. An antibody which specifically binds to at least one PS116 epitope, wherein said PS116 epitope is derived from an amino acid sequence having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, SEQUENCE ID NO 29, and fragments thereof.

30 21. An assay kit for determining the presence of PS116 antigen or anti-PS116 antibody in a test sample, comprising a container containing a PS116 polypeptide having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, SEQUENCE ID NO 29, and fragments thereof.

22. The assay kit of claim 21, wherein said polypeptide is attached to a solid phase.

5 23. An assay kit for determining the presence of PS116 antigen in a test sample, comprising a container containing an antibody which specifically binds to a PS116 antigen which comprises at least one PS116 epitope.

10 24. The kit of claim 23, wherein said antibody is attached to a solid phase.

15 25. A method for producing a polypeptide comprising at least one PS116 epitope, said method comprising incubating host cells that have been transfected with an expression vector containing a polynucleotide sequence encoding a polypeptide, wherein said polypeptide comprises an amino acid sequence having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, SEQUENCE ID NO 29, and fragments thereof.

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20 26. A method for detecting PS116 antigen in a test sample suspected of containing said PS116 antigen, comprising:

25 (a) contacting the test sample with an antibody or fragment thereof which specifically binds to at least one epitope of a PS116 antigen selected from the group consisting of SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, SEQUENCE ID NO 29, and fragments thereof, wherein said contacting is carried out for a time and under conditions sufficient for the formation of antibody/antigen complexes; and

30 (b) detecting the presence of said complexes as an indication of the presence of said PS116 antigen.

27. The method of claim 26, wherein said antibody is attached to a solid phase.

35 28. A method for detecting the presence of antibodies specific for a PS116 antigen in a test sample suspected of containing such antibodies, said method comprising:

- (a) contacting the test sample with a PS116 polypeptide, wherein said PS116 polypeptide contains at least one PS116 epitope derived from an amino acid sequence or fragment thereof having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 25,  
5 SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, SEQUENCE ID NO 29, and fragments thereof, and further wherein said contacting is carried out for a time and under conditions sufficient to allow antigen/antibody complexes to form; and  
10 (b) detecting the presence of said complexes as an indication of the presence of said antibodies specific for a PS116 antigen.

29. The method of claim 28, wherein said PS116 polypeptide is attached to a solid phase.

15 30. A cell transfected with a nucleic acid sequence encoding at least one PS116 epitope, wherein said nucleic acid sequence is selected from the group consisting of SEQUENCE ID NOS 1-12, and fragments or complements thereof.  
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20 31. A method for producing antibodies which specifically bind to PS116 antigen, comprising administering to an individual an isolated immunogenic polypeptide or fragment thereof in an amount sufficient to elicit an immune response, wherein said immunogenic polypeptide comprises at least one PS116 epitope and has at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NO 25, SEQUENCE ID NO 26,  
25 SEQUENCE ID NO 27, SEQUENCE ID NO 28, SEQUENCE ID NO 29, and fragments thereof.

30 32. A method for producing antibodies which specifically bind to PS116 antigen, comprising administering to an individual a plasmid comprising a sequence which encodes at least one PS116 epitope derived from a polypeptide having an amino acid sequence selected from the group consisting of SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, SEQUENCE ID NO 29, and fragments thereof.

35 33. A composition of matter comprising a PS116 polynucleotide or fragment thereof, wherein said polynucleotide has at least 50% identity with a  
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~~polynucleotide selected from the group consisting of SEQUENCE ID NOS 1-12, and fragments or complements thereof.~~

34. A composition of matter comprising a polypeptide containing at least one PS116 epitope, wherein said polypeptide has at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NO 25, SEQUENCE ID NO 26, SEQUENCE ID NO 27, SEQUENCE ID NO 28, SEQUENCE ID NO 29, and fragments thereof.

10 35. The test kit of claim 10 further comprising a container with tools useful for collection of said sample, wherein the tools are selected from the group consisting of lancets, absorbent paper, cloth, swabs and cups.

15 36. The assay kit of claim 21 further comprising a container with tools useful for collection of said sample, wherein the tools are selected from the group consisting of lancets, absorbent paper, cloth, swabs and cups.

20 37. The test kit of claim 23 further comprising a container with tools useful for collection of said sample, wherein the tools are selected from the group consisting of lancets, absorbent paper, cloth, swabs and cups.

38. A gene, or fragment thereof, which codes for a PS116 protein having an amino acid sequence with at least 50% identity to SEQUENCE ID 25.

25 39. A gene, or fragment thereof, comprising DNA having at least 50% identity with SEQUENCE ID NO 11 or SEQUENCE ID NO 12.

30 40. The method of claim 1, wherein the presence of said target PS116 polynucleotide in said test sample is indicative of prostate disease.

41. The method of claim 3, wherein the presence of said amplicon is indicative of prostate disease.

35 42. The method of claim 6, wherein the presence of said second stage reaction product is indicative of prostate disease.

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43. The method of claim 26, wherein detection of said complexes is indicative of prostate disease.

44. The method of claim 28, wherein detection of said complexes is  
5 indicative of prostate disease.

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